REMARKS:

With careful attention to the Examiner's comments in the Office Action dated February 2, 2007, the Application has been amended to place it in condition for allowance. Claims 1 – 40 are pending in the application. Claims 1 – 40 stand rejected under 35 U.S.C. 102(e) and 35 U.S.C. 103(a). Claims 1 – 40 include independent claims 1, 11, 19, 29 and 37.

Since there are erroneously included numerals "15" in claim 15 and "25" in claim 23, Applicant respectfully submits amendment of the claims 15 and 23, which deletes the erroneously included numerals "15" and "25," respectively.

CLAIM REJECTIONS:

With careful attention to the Examiner's rejections in the Official Action dated February 2, 2007, Applicant submits its request for reconsideration.

35 U.S.C. §102

LEGAL PRINCIPLE - A claim is anticipated under 35 U.S.C. 102 only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Company, 814 F.2d 628 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim of the invention. Richardson v. Suzuki Motor Company, 868 F.2d 1226, 1236 (Fed. Cir. 1989). With regard to "inherency," the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency or characteristic. In re Rijckaert, 9 F.3d, 1531, 1534 (F.2d 1993). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be recognized by persons of ordinary skill. Inherency, however, may be established by

probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. In re Robertson, 169 F.3d, 743, 745. Also, a reference cannot anticipate a claim if there is any structural difference, even if the prior art device performs the function of the claim. In re Ruskin, 347 F.2d 843.

Claims 1 – 5 and 8 – 40

The Examiner asserts that all the limitations of Claims 1 – 5 and 8 – 40 of the present invention are anticipated by the Turba et al. reference (U.S. Patent Publication. No. 7,124,135 - hereinafter "Turba et al. reference").

However, the Turba et al. does not anticipate all limitations of claims 1 - 5 and 8-40. The Turba et al. reference discloses an enhanced interface between a legacy data base management system and Internet servers employing XML protocol. Referring to col. 2, lines 44 – 49 and col. 3, lines 15 – 22 of the Turba et al. reference, the Turba et al. acknowledged problems of the conventional art, associated with implementation of communication between the Internet servers and the legacy data base management system with the XML format. To solve this problem, the Turba et al. provides an XML document having a call to native script and embeds the native script into a service responding to the converted XML document. *See col. 3, lines 30 – 42*. The Turba et al. reference provides the enhanced interface to solve the problems when the XML document is converted into a various internal format within the legacy data base management system.

On the other hand, the present invention provides a method of converting documents of the legacy data processing systems in various data formats into XML data in order to integrate the various data from a plurality of legacy data processing systems in a pharmaceutical development enterprise. The present invention allows users to integrate data from various legacy data processing systems, such as an active pharmaceutical ingredient (API) data processing system, laboratory information management systems (LIMS), a clinical data management system (DMS), by converting the legacy data in various internal data format into the XML data format. The Turba et al. reference is

related to conversion of the XML data format into the internal data format of the legacy data base management system whereas the present invention is related to the conversion of the legacy data in various internal data format into the common XML data format. The various "XML-to-Legacy" processes taught by Turba cannot perform the task converting various legacy formats to a common XML.

With regard to Claim 1 of the present application as amended, it recites three elements: 1) retrieving data from a plurality of legacy data processing systems useful in aspects of pharmaceutical development; 2) reformatting the retrieved data into a common XML data format; and 3) presenting the reformatted XML data to a user through a browser client program. The Examiner asserts that the step 2) of "reformatting the retrieved data into XML data" corresponds to the paragraph 20, lines 2-5 of the Turba et al. reference ("a technique which can embed native code into a service that will handle data received as an XML message during processing of a service request by a legacy data base management system"). The technique for embedding native code or script is not relevant to the present invention. Further, although the Turba et al. reference discloses the XML data format, it only discloses conversion of the XML data format into the internal data format of the legacy data base management system. Turba et al. does not teach conversion of the legacy data found in various internal data formats and retrieving the data from a plurality of legacy data processing systems and converting the data into a common XML data format. It is clear from the paragraph 20, lines 6 – 12 of the Turba et al., cited by the Examiner, "the present invention must first provide an interface herein referred to generically as a gateway, which translates transaction data transferred from the user over the Internet in XML format into a format from which data base management system commands and inputs may be generated." The gateway converts the XML data from the user into a data format of data base management system. It is also clear from the claim 1 of the Turba et al., which recites "converting said XML document into said internal format within said legacy data base management system." Further, the Turba et al. reference does not disclose the step 3) of presenting the reformatted XML data to a user through a browser client program. The Turba et al. reference only discloses the step of receiving transaction data transferred from the user in XML format. As such,

Turba et al. does not disclose each and every elements of claim 1, particularly, the step of "reformatting the retrieved data into XML data."

With regard to claim 2 of the present application as amended, the Examiner asserts that the step of generating regulatory submission information from the retrieved data corresponds to the paragraph 20, lines 14-15 of the Turba et al. reference ("[t]hus, as a minimum, the gateway must make these format and protocol conversions.") since the retrieved data is being changes in to the different format and presented in XML. However, the step of generating regulatory submission information is not data format conversion process. The regulatory submission information recited in claim 2 as amended is required by regulatory agencies associated with the pharmaceutical development. Further, claim 2 depends from the independent claim 1 and has all the limitations thereof. As such, the dependent claim 2 and claim 3 depending there from are now in condition for allowance for the same reasons asserted for claims 1 and 2 above.

With regard to claims 4 and 5 of the present application, the Examiner asserts that each of the steps of "displaying a synthesis plan for development of a pharmaceutical wherein the synthesis plan is derived from the retrieved data" and "displaying chemical synthesis information including molecular drawings and chemical reaction information, wherein the chemical synthesis information is derived from the retrieved data" is disclosed in the Turba et al. reference. However, the Turba et al. reference does not disclose anything related to chemical synthesis information. Further, claims 4 and 5 depend from the independent claim 1 and have all the limitations thereof. As such, the dependent claim 4 and claim 5 depending there from are now in condition for allowance for the same reasons asserted for claim 1 above.

With regard to claims 8 - 10 of the present application, they depend from the independent claim 1 and have all the limitations thereof. As such, the dependent claims 8 and 9 and claim 10 depending there from are now in condition for allowance for the same reasons asserted for claim 1 above.

With regard to Claim 11, it recites three elements: 1) a retrieval engine, responsive to user queries, for retrieving information from any of a plurality of legacy data processing systems each having at least a portion of the pharmaceutical development information; 2) an XML converter, communicatively coupled to the retrieval engine for reformatting the retrieved information as XML messages; and 3) a portal server system, communicatively coupled to the retrieval engine and to the XML converter for presenting the XML messages to a requesting user. The Examiner asserts that the step 2) of "an XML converter, communicatively coupled to the retrieval engine for reformatting the retrieved information as XML messages" corresponds to the paragraph 20, lines 2-4 of the Turba et al. reference ("a technique which can embed native code into a service that will handle data received as an XML message during processing of a service request by a legacy data base management system"). As discussed above, the technique for embedding native code or script is not relevant to the present invention. Further, although the Turba et al. reference discloses the XML data format, it only discloses conversion of the XML data format into the internal data format of the legacy data base management system. It does not disclose the XML converter for converting the legacy data in various internal data format retrieved from a plurality of legacy data processing systems into the common XML data format. Referring to claim 11 of the Turba et al., it recites "converting said XML document into said internal format within said legacy data base management system." It is also clear from the paragraph 20, lines 6 – 12 of the Turba et al., cited by the Examiner, "the present invention must first provide an interface herein referred to generically as a gateway, which translates transaction data transferred from the user over the Internet in XML format into a format from which data base management system commands and inputs may be generated." As such, Turba et al. does not disclose each and every elements of claim 11, particularly, the XML converter, communicatively coupled to the retrieval engine for reformatting the retrieved information as XML messages.

With regard to claims 12 - 17 of the present application, they depend from the independent claim 11 and have all the limitations thereof. As such, the dependent claims

12 - 17 are now in condition for allowance for the same reasons asserted for claim 1 above.

With regard to claim 18 of the present application, the Examiner asserts that the regulatory submission generator, communicatively coupled to the XML converter corresponds to the paragraph 20, lines 6-12 of the Turba et al. reference ("the present invention must first provide an interface herein referred to generically as a gateway, which translates transaction data transferred from the user over the Internet in XML format into a format from which data base management system commands and inputs may be generated.") The Examiner further asserts that the gateway works as the XML converter. However, the Turba et al. reference does not disclose the regulatory submission generator for automatically generating regulatory submission information pertaining to the pharmaceutical development information from the XML messages. Further, claim 18 depends from the independent claim 11 and has all the limitations thereof. As such, the dependent claim 18 is now in condition for allowance for the same reasons asserted for claim 11 above.

With regard to claim 19 of the present application, it recites a computer readable storage medium tangibly embodying program instructions to provide a method for pharmaceutical development data management. The method corresponds to the claim 1 of the present invention. Thus, Applicant's above remarks for claim 1 are incorporated herein.

With regard to claims 20 – 28, the Examiner notes that each of the claims corresponds to the limitations in claims 2 – 10, respectively. As such, Applicant's above remarks for each of the claims 2 - 10 are incorporated herein.

With regard to claim 29, it recites four elements: 1) receiving a request from a user to retrieve data relating to pharmaceutical development from disparate legacy database systems; 2) sending a query to the disparate legacy database systems responsive to the request from the user; 3) receiving the data relating to pharmaceutical development

from the disparate legacy database systems base on the query; and 4) collating the data and reformatting the data as standard XML format tagged data for presentation of the data to the user in various formats. The Examiner asserts that the step 1) of "receiving a request from a user to retrieve data relating to pharmaceutical development from disparate legacy database systems" corresponds to the paragraph 20, lines 1-5 of the Turba et al. reference ("The present invention overcomes the disadvantages of the prior art by providing a technique which can embed native code into a service that will handle data received as an XML message during processing of a service request by a legacy data base management system. In order to permit such functionality, the present invention must first provide an interface herein referred to generically as a gateway, which translates transaction data transferred from the user over the Internet in XML format into a format from which data base management system commands and inputs may be generated. The gateway must also convert the data base management system responses and outputs for usage on the user's Internet terminal"). The Turba et al. reference does not disclose anything related to the legacy database systems in association with the pharmaceutical development. Further, as discussed above, although the Turba et al. reference discloses the XML data format, it only discloses conversion of the XML data format into the internal data format of the legacy data base management system. It does not disclose conversion of the legacy data in various internal data format retrieved from a plurality of legacy data processing systems into the common XML data format. Further, the Turba et al. reference does not disclose the step 4) of collating the data and reformatting the data as standard XML format tagged data for presentation of the data to the user in various formats. The Turba et al. reference only discloses the step of receiving transaction data transferred from the user in XML format. As such, Turba et al. does not disclose each and every elements of claim 29.

With regard to claim 30 of the present application, it depends from the independent claim 29 and has all the limitations thereof. As such, the dependent claim 30 is now in condition for allowance for the same reasons asserted for claim 29 above.

With regard to claims 31 - 33 of the present application, the Examiner asserts that each of the steps of "generating a template for a synthesis plan for development of a pharmaceutical wherein the synthesis plan is derived from the retrieved data relating to pharmaceutical development;" "generating a template for chemical synthesis information including molecular drawings and information derived from the retrieved data relating to pharmaceutical development;" and "generating a template for analysis data integrated with the chemical synthesis data where the analysis data is derived from the retrieved data relating to pharmaceutical development" is disclosed in the Turba et al. reference. However, the Turba et al. reference does not disclose anything related to chemical synthesis information. Further, claims 31 - 33 depend from the independent claim 29 and have all the limitations thereof. As such, the dependent claims 31 - 33 are now in condition for allowance for the same reasons asserted for claim 29 above.

With regard to claim 34 of the present application, the Examiner asserts that the step of "generating a regulatory submission formatted report from the XML reformatted data for submission" corresponds to the paragraph 20, lines 2-4 of the Turba et al. reference ("the present invention must first provide an interface herein referred to generically as a gateway, which translates transaction data transferred from the user over the Internet in XML format into a format from which data base management system commands and inputs may be generated"). However, the step of generating regulatory submission information is not a data format conversion process. The regulatory submission information recited in claim 34 as amended is required by regulatory agencies associated with the pharmaceutical development. Further, claim 34 depends from the independent claim 29 and has all the limitations thereof. As such, the dependent claim 34 and claim 35 depending there from are now in condition for allowance for the same reasons asserted for claims 29 and 34 above.

With regard to claim 36 of the present application, the Examiner notes that each of the claims corresponds to the limitations in claim 9. As such, Applicant's above remarks for claim 9 are incorporated herein.

With regard to claim 37, it recites four elements: 1) presenting a prompt to a user requesting an input which specifies retrieval of data relating to pharmaceutical development to be retrieved from disparate legacy database systems; 2) accepting and processing the user request to determine if the user request relates to generating regulatory submission information or relates to retrieving particular information for presenting to the user; 3) sending the user request to a portal collaboration user interface system operable to extract data from the disparate legacy database systems based on the request; and 4) receiving from the portal user interface system data extracted from the disparate legacy database systems collated and formatted in a standard XML format and providing the data to the user. The Examiner asserts that the step 1) of "presenting a prompt to a user requesting an input which specifies retrieval of data relating to pharmaceutical development to be retrieved from disparate legacy database systems" corresponds to the paragraph 69, lines 2-3 of the Turba et al. reference ("Window area 128 provides for the entry of any necessary or helpful input parameters. Not shown are possible prompts for entry of this data, which may be defined at the time of service request development"). However, the prompt in the Turba et al. reference does not request an input of data related to pharmaceutical development. Also, the Examiner asserts that the step 4) of "receiving from the portal user interface system data extracted from the disparate legacy database systems collated and formatted in a standard XML format and providing the data to the user" corresponds to the paragraph 32, lines 4-6 of the Turba et al. reference ("In addition, the template component gives the user a wide range of languages in which to program their user interface including HTML, HDML, XML, WML, JavaScript, Vbscript, and WMLscript. This tremendous flexibility gives the user a fast and effective way to tailor their user interface"). The step 4) of the present invention is not use of the XML data format for the user interface itself as disclosed in the Turba et al. reference. According to the present invention, the user receives data extracted from the disparate legacy database systems collated and formatted into a standard XML format from various data formats, in response to the user's request, wherein the received data have been extracted from the disparate legacy database system. The Turba et al. reference does not disclose the step 4). As such, Turba et al. does not disclose each and every elements of claim 37.

With regard to claims 38 - 40 of the present application, the Examiner asserts that each of the steps of "displaying a synthesis plan for development of a pharmaceutical wherein the synthesis plan is derived from the extracted data;" "displaying chemical synthesis information including molecular drawings and chemical reaction information, wherein the chemical synthesis information is derived from the extracted data;" and "displaying analysis data integrated with the display of the chemical synthesis information wherein the analysis data is derived from the extracted data" is disclosed in the Turba et al. reference. However, the Turba et al. reference does not disclose anything related to chemical synthesis information. Further, claims 38 - 40 depend from the independent claim 37 and have all the limitations thereof. As such, the dependent claim 38 and claims 39 and 40 depending there from are now in condition for allowance for the same reasons asserted for claim 38 above.

35 U.S.C. §103

LEGAL PRINCIPLE - To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. The teaching or suggestion to make the claim combination or combine the references and the reasonable expectation of success must both be found in the prior art and not based on the Applicant's disclosure. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991).

With regard to the first criteria for a suggestion or motivation to modify or combine references, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The test for an implicit showing is what the combined teachings, knowledge of one of

ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. In re Kotzab, 217 F.3d 1368 (Fed. Cir. 2000). However, the mere fact that the references can be combined or modified does not render the result and combination obvious unless the prior art also suggests the desirability of a combination. In re Mills, 916 F.2d 680 (Fed. Cir. 1990). The fact that the prior art references may be capable of being modified to function as the claimed apparatus is not enough, there must be a suggestion or motivation in the reference to do so. In re Mills, 916 F.2d 682 (Fed. Cir. 1990). Further, a statement that modifications of the prior art to achieve the claimed invention would have been well within the ordinary skill of the art because the prior art relied upon teach that all aspects of the claimed invention were individually known is again not enough. The prior art is not sufficient to establish obviousness without some objective reason to combine the teachings of the references. In re Kotzab, 217 F.3d 1368 (Fed. Cir. 2000), also see In re Sang Su Lee, 277 F.3d 1338 (Fed. Cir. 2002). Also, the proposed modification would render the prior art being modified unsatisfactory for its intended purpose and there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900 (Fed. Cir. 1984).

Claims 6 and 7

The Examiner rejected Claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over the Turba et al. reference in view of Wang et al. (U.S. Publication No. 6,727,096 – hereinafter "Wang et al. reference").

Both claims 6 and 7 depend from the independent claim 1 and have all the limitations thereof. As discussed above, the Turba et al. reference does not teach or suggest all the limitations of the claim 1, particularly, the step 2) of "reformatting the retrieved data into XML data. Further, Wang et al. does not teach or suggest this limitation. As such, claims 6 and 7 are therefore not made obvious by the Turba et al. and Wang et al. references, either alone or in combination.

If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard.

Respectfully submitted,

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